(c) if so, the steps taken in that regard?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (c) The Government is aware of these traditional medicines and practices. The Central Council for Research in Ayurveda and Siddha and Central Council for Research in Unani Medicines which are autonomous research organisations funded by the Government have documented over 10,000 folklores under their enthno-botanical survey. This is a continuing programme and evaluation of efficacy has been initiated selectively.

Investigational New Drug application norms

262. DR. MAHESH CHANDRA SHARMA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is necessary for Investigational New Drug (IND) applications to contain data from toxicity studies;

(b) whether it is a fact that as per Drugs and Cosmetics Act, toxicity studies are required at least on two animal species *viz.*, rat and dog;

(c) whether it is necessary to get protocol for dog studies approved from CPCSEA, a Committee responsible for animal welfare;

(d) if so, how many such protocols have been approved by CPCSEA during the last two years; and

(e) how many IND applications have been received by Drug Controller General of India?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) Yes. Sir, Data required for processing Investigational New Drugs (IND) applications *inter alia* includes toxicity study reports.

(b) Yes. Sir, the requirements in terms of toxicity studies on rodents (*e.g.* rats) as well as on non-rodents (*e.g.* dogs), for processing new drug applications, are laid down in Schedule Y of the Drug and Cosmetic Act and Rules thereunder.

(c) and (d) Yes Sir, a sub committee of the CPCSEA (Committee for the purpose of Control and Supervision of Experiments on Animals), which is a body under the Ministry of Social Justice and Empowerment, have examined 18 projects involving large animals, (non-rodents), of which 10 projects, including dog studies, have been approved.

(e) During the last 2 years, three Investigational New Drugs (IND) applications have been received by the office of the Drug Controller of India.

Norms for clinical trials of drugs

263. SHRI SANJAY NIRUPAM: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the proposal mooted by the R&D Sub-Committee of CII's National Committee on Drugs and Pharmaceuticals, seeking changes in norms for clinical trials of drugs in the country; if so, the details thereof;

(b) the salient features of existing norms of clinical trials; and

(c) whether Government propose to amend the existing norms, on the basis of suggestions so received; if so, by when?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) No such proposal has been received.

(b) At present clinical trials in the country are governed by the provisions contained in Schedule Y of the Drugs and Cosmetics Act and Rules thereunder. The level of clinical trials required to be carried out before a new drug is approved for manufacture/marketing depends to an extent on the status of that drug in other countries.

If it has been already approved for manufacture or marketing and adequate documentation regarding the clinical trials done in that connection is available, then only Phase III trials, as laid down in Schedule Y of the Drug and Cosmetics Rules is required.

If the drug has not been approved elsewhere, then trials are